DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

§ 5164

JAN 10 2005

Food and Drug Administration
Center for Devices and
Radiological Health
2098 Gaither Road
Rockville, MD 20850

WARNING LETTER

VIA FEDERAL EXPRESS

Mr. Niels Erik Johansen, President
Faaborg Rehab Technic ApS
Smedemestervej 9
Faaborg, 5600
Denmark

Dear Mr. Johansen:

During an inspection of your firm located in Faaborg, Denmark on August 23, 2004 through August 27, 2004, an investigator from the United States Food and Drug Administration (FDA) determined that your firm manufactures non-AC-powered patient lifts and other medical devices. These products are devices within the meaning of section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. § 321(h)).

This inspection revealed that these devices appear to be adulterated within the meaning of section 501(h) of the Act (21 U.S.C. § 351(h)), in that the methods used in, or the facilities or controls used for, their manufacture, packing, storage, or installation are not in conformity with the Current Good Manufacturing Practice (CGMP) requirements of the Quality System (QS) regulation found at Title 21, Code of Federal Regulations (CFR), Part 820. Significant violations include, but are not limited to, the following:

1. Failure to validate with a high degree of assurance a process that cannot be fully verified by subsequent inspection and test, as required by 21 CFR 820.75(a). For example, there is no documentation to show that three different welding processes used to weld Faaborg Lifts (Series PL, VL, and Nordic) were validated. The welding processes include [redacted].

2. Failure to establish and maintain procedures for implementing corrective and preventive action, as required by 21 CFR 820.100(a). For example, your firm does not have any written corrective and preventive action procedures.

3. Failure to adequately establish and maintain procedures for implementing corrective and preventive action, which include requirements for verifying or validating the corrective and preventive action to ensure that such action is effective and does not adversely affect the finished device, as required by 21 CFR 820.100(a)(4). For example, on January 28, 1997, your firm changed

the hanger bar and bolt from a 2-point hanger bar and bolt to a 3-point hanger bar and bolt on the PL, VL, and Nordic series patient lifts. There is no documentation that demonstrates that the change was effective and did not adversely affect the finished device. Additionally, the test data and protocols, [redacted], dated August 10, 2004, for Faaborg Lifts [redacted] washer and ball bearing studies do not include test acceptance criteria.

4. Failure to establish and maintain procedures for receiving, reviewing, and evaluating complaints by a formally designated unit, as required by 21 CFR 820.198(a). For example, your firm does not have written complaint handling procedures.

5. Failure to promptly review, evaluate, and investigate any complaint representing an event which must be reported to FDA, as required by 21 CFR 820.198(d). For example, complaints representing events that are MDR reportable were not promptly reviewed, evaluated and investigated by a designated individual. Specifically, there is no documentation to show that an investigation of an MDR reportable event was conducted. The MDR event, dated March 25, 2004, re: Faaborg PL 250, reported, "Resident was transferred from wheelchair with a Faaborg Lift when lift malfunctioned. Resident fell to floor." On January 14, 2004, an x-ray of the resident showed superior and inferior pubic ramus fractures.

6. Failure to develop documented instructions, standard operating procedures (SOP's), and methods that define and control the manner of production, as required by 21 CFR 820.70(a)(1). For example, your firm does not have written instructions for any of its welding processes.

7. Failure to establish and maintain procedures to ensure that equipment is routinely calibrated, inspected, checked, and maintained, as required by 21 CFR 820.72. For example, procedures to ensure that equipment is routinely calibrated have not been established. Specifically, there is no calibration program established for the inspection, measuring, and test equipment used during production and product development. Additionally, certain measuring and test equipment is not suitable for its intended purposes or capable of producing valid results. Specifically, calibration was not performed for the following measuring and test equipment:

   a. [redacted]
   b. [redacted]
   c. [redacted]
   d. [redacted]
   e. [redacted]

8. Failure to ensure that all equipment used in the manufacturing process meets specified requirements and is appropriately designed, constructed, placed, and installed to facilitate maintenance, adjustment, cleaning, and use, as required by 21 CFR 820.70(g). For example, there are no electrostatic discharge (ESD) controls installed in an area where PC board testing and assembly activities occur.

9. Failure to establish and maintain procedures for identifying training needs and to ensure that all personnel are trained to adequately perform their assigned responsibilities, as required by 21 CFR 820.25(b). For example, there are no employee training records maintained.

10. Failure to establish and maintain acceptance procedures to ensure that specified requirements for in-process product are met, as required by 21 CFR 820.80(c). For example, your firm's in-process testing procedure does not include the maximum capacity or lift actuator and leg-spreader amp specifications for the [redacted] lift.

11. Failure to establish and conduct quality audits to assure that the quality system is in compliance with the established quality system requirements and to determine the effectiveness of the quality system, as required by 21 CFR 820.22. For example, your firm's March 2004 internal audits failed to review the following Quality System regulation elements: Corrective and Preventive Action; Complaint Handling; Purchasing Controls; Production and Process Controls; Process Validation; Acceptance Activities; and Inspection, Measuring, and Test Equipment. Your firm's audit procedure, [redacted], does not ensure that quality audits are performed to determine the effectiveness of the quality system and to assure that the quality system is in compliance with 21 CFR 820. Additionally, your firm did not conduct quality audits prior to March 2004.

12. Failure to establish procedures for management review with executive responsibility to review the suitability and effectiveness of the quality system at defined intervals and with sufficient frequency, as required by 21 CFR 820.20(c). For example, your firm does not have written management review procedures

Additionally, the above-stated inspection revealed that your devices are misbranded under section 502(t)(2) of the Act, in that your firm failed or refused to furnish any material or information as required by section 519 respecting the device and the Medical Device Reporting (MDR) regulation, 21 CFR, Part 803. For example, one deviation was your failure to develop, maintain, and implement proper written MDR procedures, as required by 21 CDR 803.17.

This letter is not intended to be an all-inclusive list of violations at your facility. It is your responsibility to ensure compliance with applicable laws and regulations administered by FDA. The specific violations noted in this letter and in the Inspectional Observations, Form FDA 483 (FDA 483), issued at the closeout of the inspection may be symptomatic of serious problems in your firm's manufacturing and quality assurance systems. You should investigate and determine the causes of the violations, and take prompt actions to correct the violations and to bring your products into compliance.

Given the serious nature of these violations of the Act, non-AC-powered patient lifts and other medical devices manufactured by your firm and imported or offered for import are subject to refusal of admission under section 801(a) of the Act, 21 U.S.C. § 381(a), in that they appear to be adulterated. As a result, FDA may take steps to refuse these products, known as "detained without physical examination," until these violations are corrected.

In order to remove the devices from detention, you should provide a written response to this Warning Letter as described below and correct the violations described in this letter. We will notify you if your response is adequate, and we may need to re-inspect your facility to verify that the appropriate corrections have been made. In addition, U.S. federal agencies are advised of the issuance of all Warning Letters about devices so that they may take this information into account when considering the award of government contracts.

The responses you sent dated September 1, 2004, September 16, 2004, October 12, 2004, and October 15, 2004, concerning our investigator's observations noted on the FDA 483 were received on October 15, 2004. As we stated during our meeting with you on October 25, 2004, we have not reviewed your responses yet; however, we will review the responses and communicate our comments to you. In the meantime, however, you should not delay your response to this warning letter.

Please notify this office in writing within fifteen (15) working days from the date you receive this letter, of the specific steps you have taken to correct the noted violations, including an explanation of how you plan to prevent these violations, or similar violations, from occurring again. Include all documentation of the corrective action you have taken. If you plan to make any corrections in the future, include those plans with your response to this letter as well. If the documentation is not in English, please provide a translation to facilitate our review.

Please direct your response to Carolyn Niebauer, Chief, General Hospital Devices Branch, HFZ-333, Office of Compliance, Center for Devices and Radiological Health, 2098 Gaither Road, Rockville, MD 20850. If you have any questions about the contents of this letter please contact Ms. Niebauer at (240) 276-0115 or by facsimile at (240) 276-0114.

Sincerely yours,

Timothy A. Ulatowski
Director
Office of Compliance
Center for Devices and
Radiological Health